K050842

1/3

510 (K) SUMMARY

AUG 0 2 2006

1. **Submitter's Name & Address:**

Modern Medical Equipment Manufacturing Ltd

5F,Gold King Ind.Bldg.
35 Tai Lin Pai Rd.
Kwai Chung
Hong Kong

Or 1705 Dabney Rd.
Richmond
VA 23230
USA

Contact Person & Tel Nos:

Mr. Bob Stillman (Account Manager)

Phone : (1) 804-353-7160

Fax : (1) 804-353-7161

E-Mail : Bob_Stillman@modernmedical.com.hk

Date summary was prepared : November 17, 2005

2. **Device Name :**

Proprietary Name: Modern Medical Antimicrobial Wound Dressing
Modern Medical Antimicrobial Burn Dressing

Common /Usual name: Dressing

Classification Name: Dressing

3. **Identification of Predicate Device for which Substantial Equivalence is claimed :**

Predicate device for which Substantial Equivalence is claimed is identified as : Silverlon Contact Wound Dressing (K023612) of Argentum International LLC

4. **Device Description:**

Explanation of how the device functions: the devices Modern Medical Antimicrobial Wound Dressing & Modern Medical Antimicrobial Burn Dressing when placed in contact with wounds act as first aid management for minor abrasions, cuts, scrapes, scalds and burns.

Scientific concepts that form the basis for the device : the silver ions contained in the fabric of the dressings provide effective barrier against microbial contamination. The silver ions on the devices give rise to an antimicrobial barrier and hence protection against microbes

Significant physical and performance characteristics of the device (e.g. device design, material used, and physical properties):
Modern Medical Antimicrobial Wound Dressing is made up of darker viscose polyester layer and a lighter layer of non-woven cloth . The darker layer contains nano silver ions (0.5 mg per g) about 1-100 nm in diameter , these provide a barrier protection against

K050842

2/3

510 (K) SUMMARY

microbes . The lighter layer is designed to protect the wound surface. Modern Medical Antimicrobial Burn Dressing is totally made of unwoven cloth. The thicker and stronger texture also contains silver ions (2.6 mg per g) in order to form an effective barrier against microbes. It is intended to be applied directly onto the wound and cover with conventional methods.

5. **Intended use including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended:**
   The devices Modern Medical Antimicrobial Wound Dressing & Modern Medical Antimicrobial Burn Dressing are intended for the general population as first aid management for minor abrasions, cuts, scrapes, scalds and burns. The dressings should not be applied onto patients with a known sensitivity to silver. The dressing is not compatible with Magnetic Resonance Imaging and should not be in contact with electrodes or conductive gels during electronic measurements.

6. **Summary of the technological characteristics of the device compared to the predicate device :**
   Substantial equivalence to the predicate device can be shown by: the technological characteristics of the application of silver, antimicrobial properties of silver, first aid management for wounds, nature of materials allowing wrapping around burnt wounds and adherence onto the wounded surface.

7. **Assessment of Performance Data :**
   Modern Medical Antimicrobial Wound Dressing & Modern Medical Antimicrobial Burn Dressing were subjected to :

   a) the biocompatibility tests on: cytotoxicity, skin sensitization, skin irritation tests in accordance with ISO10993-Part 1 Biological Evaluation of Medical Devices;
   b) Acute Toxicity Test in accordance with ISO 10993-Part 11 ;
   c) Ames Test, In Vitro Mammalian Chromosome Aberration Test, In vitro Mammalian Cell Gene Mutation Test in accordance with ISO 10993-Part 3;
   d) Antimicrobial Preservatives Effectiveness test based on the United States Pharmacopoeia 23 Method 51 (USP 51) ;
   e) Antimicrobial Activity Assessment of Antimicrobial Medical Dressing test using the American Association of Textile Chemists & Colorists (AATCCC Test Method 147).

   The studies show that the dressings, Modern Medical Antimicrobial Wound Dressing & Modern Medical Antimicrobial Burn Dressing are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2006

Modern Medical Equipment Mfg., LTD
% E&M Engineering, Inc.
Mr. Robert Stillman
Account Manager
1705 Dabney Road
Richmond, Virginia 23230

Re: K050842
Trade/Device Name: Modern Medical Antimicrobial Wound Dressing
Modern Medical Antimicrobial Burn Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 7, 2006
Received: June 16, 2006

Dear Mr. Stillman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

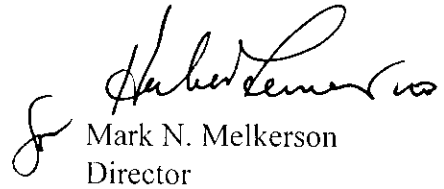
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050842

Indications for Use

510(k) Number (if known): K050842

Device Name: Modern Medical Antimicrobial Wound Dressing

Modern Medical Antimicrobial Burn Dressing

Indications for Use:

Modern Medical Antimicrobial Wound Dressing & Modern Medical Antimicrobial Burn Dressing are used for first aid management of minor abrasions, cuts, scrapes, scalds and burns.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050842